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REMARKS

Favorable reconsideration and allowance of this application are requested.

By way of the amendment instructions above, claims 41-52 have been added for consideration. Independent claim 41 is similar to original claim 30, but requires that the first and second aqueous solutions contain human or serum albumin and a di- or polyaldehyde which is reactable with the bovine or human serum albumin, respectively. In addition, the language of claim 41 is not specific as to which of the first and second aqueous solutions contains the blowing agent and the acidic titrant, respectively.

No further amendments have been proposed with respect to prior claims 30-40. Hence, claims 30-52 are presently pending in this application for which favorable reconsideration and allowance are solicited.

I. Response to Art-Based Rejections

All prior pending elected claims (i.e., 30-40) attracted a rejection based principally upon the cited Nussinovitch reference (USP 6,589,328) either alone or in combination with Wang (USP 5,922,379) and Fattman et al (USP 6,326,524). Specifically, the Examiner asserts that Nussinovitch anticipates (35 USC §102(e)) the definition of the subject invention in claims 30 and 38, while both Wang and Fattman et al, when combined with Nussinovitch are asserted to render "obvious" (35 USC §103(a)) the invention defined by claims 30-40. Applicants suggest however that none of the applied references anticipates or renders obvious the present invention.

With regard to Nussinovitch, the Examiner asserts that in Example 1 at column 5, the reference discloses combining a solution of alginate, calcium carbonate and a solution of citric acid. It appears, however, that the Nussinovitch reference may have been misinterpreted. Specifically, it is true that an alginate powder, calcium hydrogen orthophosphate and calcium carbonate are formed into an aqueous solution and then admixed with a solution of glucono-delta-lactone. However, this admixture is then

"...poured into a plastic container...and let to set there. After 48 hours, specimens were taken from the slab...." (column 5, lines 37-38) It is this "slab" – that is to say, solid material – that is then brought into contact with citric acid solution. Specifically, Nussinovitch disclose that the slab is "...immersed in citric acid solution 2%." (Column 5, line 40).

Hence, there is absolutely no disclosure that applicants can discern in Nussinovitch whereby one part of a two-part reactable solution kit contains both a proteinaceous material and a blowing agent, and wherein a second part of the two-part reactable solution kit comprises both a solution which is reactable with the proteinaceous material to form a biopolymeric material, and an acidic titrant reactable with the blowing agent sufficient to impart a cellular foam structure to thereto. Indeed, Nussinovitch's disclosure of first forming a solid material and then contacting the solid material after a considerable period of time teaches directly against a kit as defined in the present claims to form in one simple step a cellular biopolymeric material.

The cited secondary references to both Wang and Fattman et al appear to be even less pertinent than Nussinovitch. Specifically, Wang merely teaches that a ***thermoplastic*** material may be made from protein, starch, cellulosic fiber and water. Fattman et al merely teaches that foams of hydrocolloids adhesives may be made. Niether Wang nor Fattman et al disclose or suggest a kit as claimed herein whereby one part of a two-part reactable solution kit contains both a proteinaceous material and a blowing agent, and wherein a second part of the two-part reactable solution kit comprises both a solution which is reactable with the proteinaceous material to form a biopolymeric material, and an acidic titrant reactable with the blowing agent sufficient to impart a cellular foam structure to thereto. Thus, neither Wang nor Fattman et al cure the deficiencies of Nussinovitch as discussed previously.

Notwithstanding the substantive distinctions between the present invention and the applied references, there is attached hereto a Declaration Under Rule 131 which establishes an invention date of the subject matter defined by the pending claims which

antedates the filing dates of both the Nussinovitch and Fattman et al refrences. Thus, withdrawal of Nussinovitch and Fattman et al for this reason also is in order.

II. Information Disclosure Statement

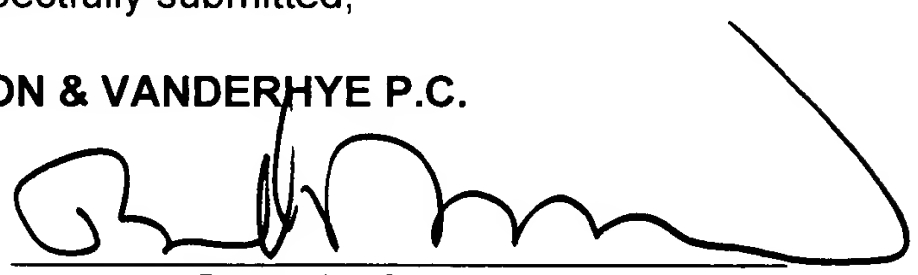
As requested in the penultimate paragraph on page 3 of the subject Official Action, there are attached hereto copies of publications cited during prosecution of copending application Serial Nos. 09/983,537 (Atty. Dkt. 1577-162) and 09/570,600 (1577-116). A copy of each listed publication is also attached for the Examiner's convenience and is listed on appropriate forms PTO-1449. Consideration of such listed publications during prosecution of the subject application is respectfully requested, for which purpose the fee required by Rule 97(c) is attached.

III. Conclusions

Every effort has been made to advance prosecution of this application to allowance. Therefore, in view of the amendments, remarks and attachments submitted herewith, applicants submit that this application is in condition for prompt allowance and Official Notice of the same is solicited.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: 

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

YUKSEL et al Atty. Ref.: **1577-164**

Serial No. **09/986,124** Group: **1617**

Filed: **November 7, 2001** Examiner: **Edward J. WEBMAN**

For: **EXPANDABLE FOAM-LIKE BIOMATERIALS AND METHODS**

* * * * * * * * * * *

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER RULE 131

Sir:

The undersigned, **K. Ümit YÜKSEL**, **Ana T. BIRD** and **Kirby S. BLACK**, hereby jointly declare and state that:

1. We are the same individuals who are named coinventors of the subject matter disclosed and claimed in the above-identified application.

2. The subject invention as claimed in the above-identified application was completed in this country prior to June 18, 1997.

3. Specifically, attached hereto as Exhibit A are date-redacted laboratory notebook pages which evidence both conception and reduction to practice of the subject invention. Specifically, the attached pages of Exhibit A evidence both conception and reduction to practice incorporating a blowing agent (Na-bicarbonate) into the albumin component of a two part proteinaceous biopolymeric system comprised of the albumin component and a glutaraldehyde component.

4. All of the events noted in Exhibit A attached hereto as Exhibit A were actually conducted and occurred in the United States of America prior to June 18, 1997.

5. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully Submitted,

25 June 2004
Date Signed

K. Ümit YÜKSEL

4/15/04
Date Signed

Ana T. BIRD

6/23/04
Date Signed

Kirby S. BLACK

From Page No. 89

Purpose Na Bicarbonate is known to increase "fizziness" in solution. Therefore, perhaps diluting albumin with Na Bicarbonate rather than $5H_2O$ will create an albumin component for BioGlue that promotes "holey cured glue". I will prepare this BSA-Na Bicarbonate solution with 50mM Na Bicarb, and evaluate its characteristics of strength and cure time, also with its ability to form natural bubbles or holes within the Glue.

Method:

1. Na Bicarbonate Soln.

Sodium Bicarb, A.C.S. [Fisher S233-500, Lot 923895, F.W. 84.01]

84.01 g/L

1 mol/L = 1M soln = 84.01 g/L

.05M soln = 4.2005 g/L

* .05M soln = 1.050 g/250mL

Prepare 250mL soln. Mix 3 hours. Check pH = 8.5

2. BSA 45% in 50mM Na Bicarb.

10% g/mL = 1

100% = 1000 mg/mL

45% = 450 mg/mL

in 25mL = 11.25 g/25mL

in 2 60cc syringes, prepare as follows.

	Syringe A	Syringe B
Tube Tare	37.00	37.70
NaBicarb, 50mM	10 mL	50 mL
Add BSA	11.25 g	11.25 g
Add more NaBicarb	2 mL	2 mL

Place on rocker overnight.

Z Pernet

Still needs more mixing after 24 hrs. Place rocker in 37°C incubator. Rock tubes at 37°C for another 24 hrs.

Add 1 more mL NaBicarb to each syringe. Continue 37°C rock.

Z Pernet

EXHIBIT A

To Page No.

Witnessed & Understood by me,	Date	Invented by	Date
		Recorded by Z Pernet	

Project No. Bio Glue

46 Book No. 16 TITLE NaBicarbonate BSA: Tensile Strength and Cure Rate of BioGlue

From Page No. 15

I. Tensile Strength:

Fill cartridges with NaBicarbonate/BSA (~4 mL) and matching volume of 10% glutaraldehyde [Sigma S5 H5015]. Skin jigs made from freshly thawed porcine skin (frozen only once). Superglue cure for skin-to-wood, ~ 4 hours.

Apply NaBicarbonat Glue to both sides of skin/jig pair (n = 5 pairs). Cure 5 min. Run on Instron Test ## 98.

BioGlue 5.09kg Tensile Test

Instron Corporation
Series IX Automated Materials Testing System

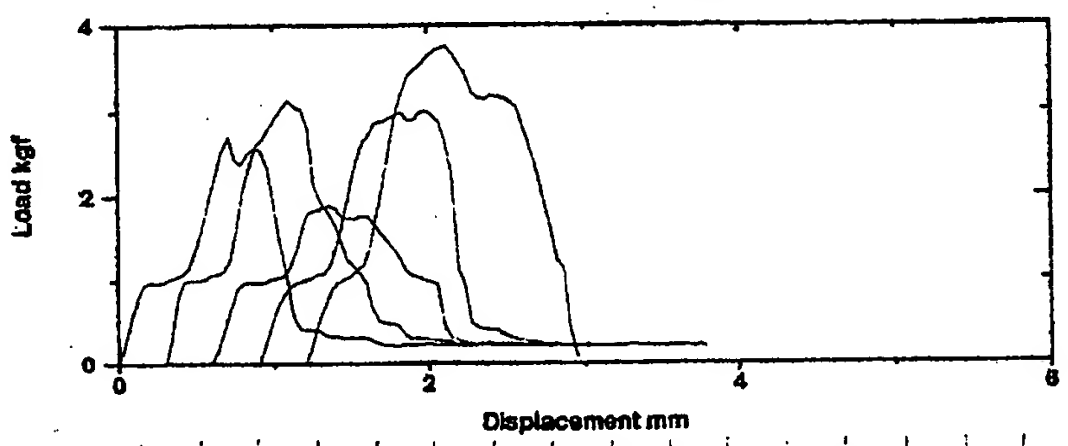
Test type: Tensile
Operator name: I. peacock
Sample Identification: 960829D
Test Date:
Sample Rate (pts/secs): 10.0000
Crosshead Speed: 25.0000 mm/min

	Load at Max.Load (gf)	Stress at Max.Load (gf/cm^2)	Glutar-aldehyde (%) ( )	Width (cm)	Thickness (cm)
1	2692.846	1035.709	10.000	2.000	1.300
2	3133.532	1205.204	10.000	2.000	1.300
3	1886.362	725.523 04	10.000	2.000	1.300
4	3009.823	1157.623	10.000	2.000	1.300
5	3760.233	1446.242	10.000	2.000	1.300

$\bar{x}$ 1211 ± 172 g/cm²

BioGlue made of NaBicarbonate BSA and Glut, superglu broke all

Sample ID: 960829D



To Page No.

Witnessed & Understood by me, Date

Invented by Date

Recorded by

om Page No. 46

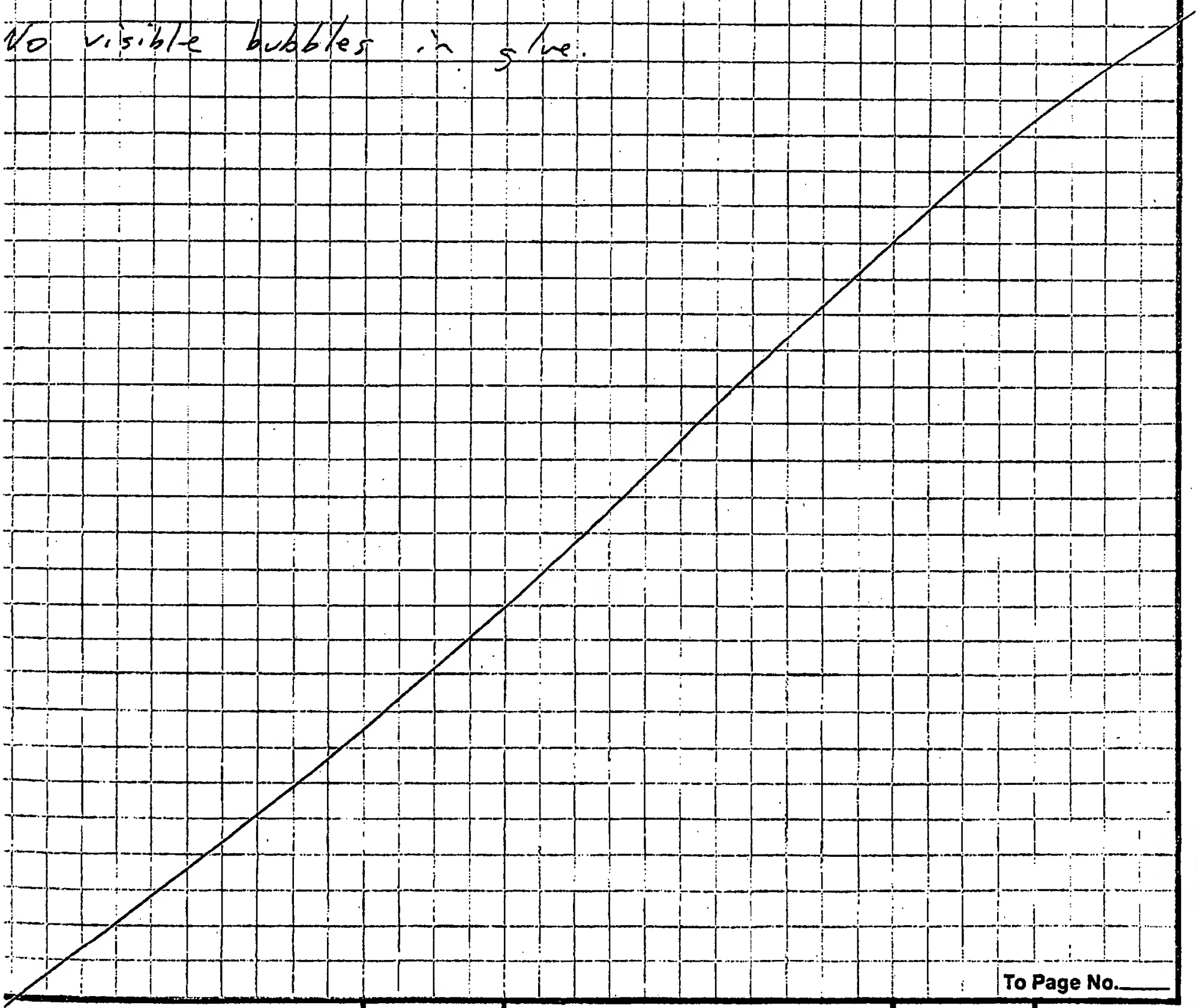
Cure rate:

From cartridges. Expel cartridge contents into petri dish and recked time to first 'stand-alone' peak.

	Time (s) to Peak
n_1	4
n_2	4
n_3	4

$\bar{y} = 4 \pm 0$ s. Cure Rate.

No visible bubbles in sline.



To Page No. _____

Witnessed & Understood by me,	Date	Invented by	Date
		Recorded by L Pearce	